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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EARL MAITLAND, Individually and on Behalf of All Those Similarly Situated,	:	**CIVIL ACTION NO.**
Plaintiff,	:	
v.	:	**CLASS ACTION COMPLAINT**
GENTA INC., RAYMOND P. WARRELL, JR. and LORETTA M. ITRI,	:	**& JURY TRIAL DEMAND**
Defendants.	:	

Plaintiff, individually and on behalf of all other persons and entities similarly situated, by their undersigned attorneys, allege upon personal knowledge as to them and their own acts, and based upon, *inter alia,* the investigation conducted by and through their attorneys as to all other matters, which investigation included, among other things, a review of the defendants' public documents and announcements, Securities and Exchange Commission ("SEC") filings, and press releases regarding Genta Inc. ("Genta" or the "Company"), information available on the Internet, including information on the U.S. Food & Drug Administration ("FDA") web site, FDA regulations and guidelines, and their attorneys' knowledge of FDA regulatory procedures and actions, as follows:

NATURE OF THE ACTION

1. This is a class action on behalf of all persons and entities who purchased Genta securities during the period from September 10, 2003 through and including May 3, 2004 (the "Class Period"), to recover damages caused by defendants' violations of the federal securities laws. During the Class Period, defendants disseminated to the investing public false and misleading statements and press releases concerning the purported clinical evidence of the safety of the Company's drug, Genasense, as a treatment for advanced melanoma, a deadly type of skin cancer, and the alleged prospects for U.S. Food and Drug Administration ("FDA") approval of the Company's New Drug Application ("NDA") for Genasense.

2. Genasense is an oncology drug which attempts to target directly the biochemical pathway whereby cancer cells are ultimately killed by chemotherapy. Genasense attempts to inhibit the production of a protein that is found in malignant melanoma and may be a cause of resistance to anti-cancer therapy. Genta's NDA for Genasense seeks approval for Genasense (G3139) in combination with dacarbazine (DTIC) for the treatment of patients with advanced melanoma who have not received prior chemotherapy.

3. Advanced melanoma is the most deadly form of skin cancer because it has spread throughout the body forming secondary tumors. The incidence of the disease has increased more rapidly than any other cancer, and has more than doubled in the last 30 years. In 2002, almost 54,000 cases of malignant melanoma were diagnosed. Melanoma is the number one cause of cancer death in women aged 25 to 30, and it ranks second in incidence to breast cancer in women 30 to 34. Globally, 132,000 melanoma skin cancers will occur every year, according to the World Health Organization.

4. Genta conducted a Phase 3 clinical trial of Genasense (G3139) plus dacarbazine (DTIC), comparing dacarbazine alone as first line chemotherapy for metastatic melanoma. During the Class Period, defendants falsely represented to the investing public that Genasense did not appear to be associated with serious adverse reactions in the Phase 3 clinical trial. In fact, defendants knew that the use of Genasense was associated with increased toxicity and discontinuations due to adverse events, and that FDA approval of the Genasense NDA was unlikely because the increased toxicity and adverse events associated with the use of Genasense outweighed its marginal benefits. Specifically, defendants knew that (a) 69 (18.6%) patients discontinued therapy for adverse events on the G3139 arm versus 39 (10.8%) on the DTIC arm alone; (b) the rate of serious adverse events was 40% on the G3139 arm versus 27% on DTIC alone; (c) all toxicities were more frequent on the Genasense arm; (d) the frequency of grade 3-4 adverse events, serious adverse events and treatment emergent adverse events leading to discontinuation were all higher on the Genasense arm; (e) the incidence of thrombocytopenia, a serious bleeding disorder characterized by a marked decrease in the number of blood platelets, was 28.8% in the Genasense arm, compared with 11.1% in the DTIC arm; (f) pyrexia (fever) was three times as frequent on the Genasense arm with 53.1% in the Genasense arm, compared to 17.5% on the DTIC arm; (g) neutropenia (significantly reduced white blood cells) and anorexia were twice as frequent with Genasense; (h) upper extremity thrombosis (blood clots) occurred in 5% of the patients receiving Genasense, compared with .8% of the patients receiving DTIC alone; (i) in the Genasense arm, 18.6% of patients discontinued treatment permanently, compared with 10.8% on the DTIC arm; and (j) since the dosing of DTIC was identical on the two arms, toxicity increases were due to the addition of G3139.

5. On April 30, 2004, the staff of the Oncologic Drugs Advisory Committee (ODAC) of the FDA stated in briefing materials in advance of the May 3, 2004 ODAC meeting that the Phase 3 clinical trial of Genasense failed to demonstrate a survival benefit, which was the primary trial endpoint. However, small but unreliable benefits were seen for progression-free survival (PFS) and response rates (RR). The staff also stated: "Uncertainty also exists regarding whether an improvement in PFS and RP of this magnitude outweighs the increase in toxicity seen with the combination [of Genasense and dacarbazine.]: . . . Survival was not improved and toxicity was increased." As a result of this announcement, the price of Genta shares dropped $5.83 or 40.4% to close at $8.60 on the Nasdaq market on an unusually high volume of over 30 million shares traded.

6. On May 3, 2004, the ODAC ruled by a 13-3 vote that, in the absence of increased survival, the evidence presented did not provide substantial evidence of effectiveness to outweigh the increased toxicity of Genasense. As a result of this announcement, the price of Genta shares fell more than $3 per share, to close at $5.11 on May 3, 2004 at a high volume of over 17 million shares traded.

JURISDICTION AND VENUE

7. The claims asserted herein arise under and pursuant to sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78j(b) and the rules and regulations promulgated thereunder by the SEC, including Rule 10b-5, 17 C.F.R. § 240.10b-5.

8. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. §1331.

9. Venue is proper in this Judicial District pursuant to section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Many of the acts and transactions constituting the violations of law alleged

herein, including the preparation and dissemination to the investing public of false and misleading information, occurred in substantial part in this Judicial District. In addition, Genta maintains its principal place of business within this Judicial District.

10. In connection with the acts, transactions and conduct alleged herein, defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including the United States mails, interstate telephone communications and the facilities of the national securities exchanges.

THE PARTIES

11. Plaintiff Earl Maitland purchased Genta securities during the Class Period, as set forth in his Certification attached hereto, and was damaged as a result thereof.

12. Defendant Genta is incorporated under the laws of the state of Delaware and maintains its principal place of business at Two Connell Drive, Berkeley Heights, New Jersey 07922. As of March 11, 2004, Genta had approximately 77 million shares of common stock outstanding. During the Class Period, Genta's common stock was actively traded on the NASDAQ under the ticker symbol "GNTA."

13. Genta is a pharmaceutical company which describes itself as "focused on delivering innovative products for the treatment of patients with cancer." According to the Company, Genasense inhibits production of a protein made by cancer cells that is thought to block chemotherapy-induced cell death. The Comapny has stated that by reducing the amount of that protein in cancer cells, Genasense may enhance the effectiveness of current treatments for advanced melanoma.

14. Defendants had a duty to promptly disseminate truthful and accurate information with respect to Genasense and to promptly correct any public statements issued by or on behalf of the Company which had become false or misleading. As detailed below, defendants have failed to comply with these obligations.

15. Defendants knew or recklessly disregarded the fact that the misleading statements and omissions complained of herein would adversely affect the integrity of the market for the Company's securities and would cause the price of the Company's securities to become artificially inflated. Defendants acted knowingly, or in such a reckless manner as to constitute a fraud and deceit upon plaintiff and the other members of the class.

16. Defendant Raymond P. Warrell, Jr., M.D. ("Warrell"), has been the Company's Chief Executive Officer since December 1999 and Chairman of the Board since January 2001. Defendant Loretta M. Itri, M.D., ("Itri") has been the Company's President, Pharmaceutical Development and Chief Medical Officer since May 2003. Defendants Warrell and Itri are sometimes referred to herein as the "Individual Defendants."

17. The Individual Defendants, by reason of their direct and substantial management positions and responsibilities during the time relevant to this Complaint, were "controlling persons" of Genta within the meaning of Section 20 of the Exchange Act and possessed the power and influence to control Genta and exercised such control to cause the Company to engage in the violations and improper practices complained of herein. Because of their positions as officers of Genta, each had the adverse non-public information about the data from the Phase 3 clinical trial of Genasense in the treatment of advanced melanoma, which was misrepresented and concealed as set forth herein.

CLASS ACTION ALLEGATIONS

18. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons who purchased Genta securities during the Class Period, and who suffered damages thereby (the "Class"). Excluded from the Class are defendants, any entity in which they have a controlling interest or is a parent or subsidiary of or is controlled by the Company, and the officers, directors, employees, affiliates, legal representatives, heirs, predecessors, successors and assigns of defendants.

19. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes there are, at a minimum, thousands of members of the Class who traded during the Class Period. The Company had in excess of 77 million shares outstanding as of March 11, 2004.

20. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) whether the Company issued false and misleading statements during the Class Period;

(c) whether defendants acted knowingly or recklessly in issuing false and misleading statements;

(d) whether the market prices of the Company's securities during the Class Period were artificially inflated because of defendants' conduct complained of herein; and

(e) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

21. Plaintiff's claims are typical of the claims of the members of the Class as plaintiff and members of the Class sustained damages arising out of defendants' wrongful conduct in violation of federal law as complained of herein.

22. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class actions and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

23. A class action is superior to other available methods for the fair and efficient adjudication of the controversy since joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by the individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for the Class members individually to redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

24. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the securities of the Company traded in an efficient market;

(d) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(e) plaintiff and members of the Class purchased their Genta securities between the time defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

25. Based upon the following, plaintiff and members of the Class are entitled to the presumption of reliance upon the integrity of the market.

NO STATUTORY SAFE HARBOR

26. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements pleaded in this complaint, because none of the statements pleaded herein were identified as "forward-looking statements" when made. Nor did meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the statements accompany those statements. To the extent that the statutory safe harbor does apply to any statements pleaded herein which are deemed to be forward-looking, the defendants are liable for those false forward-looking statements, because, at the time each of those statements were made, the speaker actually knew the forward-looking statement was false and/or the statement was authorized and/or approved by an executive officer of the Company, who actually knew that those statements were false when made.

BACKGROUND FACTS

27. The Phase 3 trial for the use of Genasense in combination with dacarbazine for the treatment of advanced melanoma enrolled patients at 140 sites from 12 different counties. A total of 771 patients who had not been previously treated with chemotherapy were randomly assigned to

receive dacarbazine, a standard chemotherapy drug, alone or in combination with Genasense. The primary endpoint was to compare the overall survival between the two treatment arms. Secondary endpoints included comparative analyses of progression-free survival (PFS) and tumor response (RR).

A. Materially False and Misleading Statements During the Class Period

28. On September 10, 2003, Genta announced the results of the Phase 3 clinical study of Genasense and submitted the first portion of the NDA to the FDA. In a press release on the *PR Newswire European*, defendants announced the following results:

- Analysis of all patients on an intent-to-treat (ITT) basis showed that the addition of Genasense to dacarbazine resulted in a median survival of 9.1 months, compared with 7.9 months for patients treated with dacarbazine alone (P=0.184).

- For patients treated per-protocol who have completed a minimum follow-up of 12 months (N=480), the addition of Genasense resulted in a median survival of 10.1 months, compared with 8.1 months for dacarbazine alone (P=0.035).

- For the ITT population (n=771), patients treated with Genasense plus dacarbazine showed a significant increase in median progression-free survival to 78 days, compared with 49 days for patients treated with dacarbazine alone (P=0.001).

- For the ITT population (n+771), patients treated with Genasense plus dacarbazine achieved an antitumor response rate of 11.7% (using RECIST criteria), compared with 6.8% for patients treated with dacarbazine alone (P=0.019).

Defendants also stated that the **"addition of Genasense to dacarbazine did not appear to be associated with serious, previously unreported adverse reactions compared with the use of dacarbazine alone."** Defendant Itri stated: "These results have been observed in a disease that is notoriously unresponsive to standard therapy and for which no drug has shown a survival advantage.

We believe the current data support the NDA submission we have initiated using provisions granted under the 'Fast Track' designation for Genasense." The statements regarding adverse reactions and their significance were materially false and misleading for the reasons set forth in paragraph 4 above.

29. In a conference call on September 10, 2003 to discuss the Phase 3 clinical results of Genasense for advanced melanoma, defendant Warrell answered the following questions by Eric Indy, a Merrill Lynch analyst:

> **Eric Indy**: OK. And then, with respect to the adverse events, you said that there was nothing that had not been previously reported. Can you talk about those that had not been – or that had been previously reported, just so I understand what the safety profile of the product is?
>
> **Raymond P. Warrell**: Yes. The safety profile is characterized by certain kinds of common reactions. The most common is a low grade fever. That usually appears in the first and second day and then goes away, really, without any therapy. No one, to my knowledge, has ever had to drop out of the program due to fever.

Defendant Warrell's statement was materially false and misleading for the reasons set forth in paragraph 4 above.

30. The NDA was completed on December 8, 2003 and on February 6, 2004, Genta announced that the FDA had accepted the NDA. In addition, Genta announced on February 6, 2004 that the FDA granted Priority Review status to the application. Defendant Itri stated: "This New Drug Application represents the first clinical indication for a drug that promotes chemotherapy-induced apoptosis, the first systemic use of an antisense thereapy, and potentially the first new drug for patients with advanced melanoma in almost 30 years." Defendant Itri's statement was materially false and misleading for the reasons set forth in paragraph 4 above.

31. During a February 11, 2004 conference call with analysts, defendant Warrell stated:

> **We believe the application as submitted in December is approvable as is.** Other than the routine safety update in April, we have no plans to reanalyze the efficacy [in the submission] during the review period unless specifically requested by the agency. **. . . Safety data show a modest increase in neutiopenia and fever [which] appears quite acceptable from an oncology point of view**.

Defendant Warrell's statements were materially false and misleading for the reasons set forth in paragraph 4 above.

32. Genta's Form 10-K for the year ending December 31, 2003, which was filed with the SEC on March 12, 2004, stated with respect to the Phase 3 trial results:

> The addition of Genasense TM to dacarbazine did not appear to be associated with serious, previously unreported adverse reactions compared with the use of dacarbazine alone.

This statement was materially false and misleading for the reasons set forth in paragraph 4 above.

SCIENTER ALLEGATIONS

33. As alleged herein, defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued or disseminated by them were materially false and misleading and/or omitted to state material facts necessary to make their statements not misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

34. As the Chief Executive Officer and Chief Medical Officer of the Company, defendants Warrell and Itri participated in creating, editing, and reviewing the quarterly safety reports to the FDA detailing adverse events experienced by patients in the trials, the Adverse Experience Reports required to be submitted to the FDA containing similar information and the Case

Report Forms in which all patient data from the trials were recorded. As a result, defendants knew or recklessly disregarded the fact that their representations about the safety of Genasense were materially misleading.

COUNT I

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 of the Securities and Exchange Commission

35. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

36. This Count is asserted against defendants and is based upon section 10(b) of the 1934 Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder.

37. During the Class Period, defendants directly engaged in a common plan, scheme, and unlawful course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business which operated as a fraud and deceit upon plaintiff and the other members of the Class, and made various deceptive and untrue statements of material facts and omitted to state material facts in order to make the statements made, in light of the circumstances under which they were made, not misleading to plaintiff and the other members of the Class. The purpose and effect of said scheme, plan, and unlawful course of conduct was, among other things, to induce plaintiff and the other members of the Class to purchase Genta securities during the Class Period at artificially inflated prices.

38. During the Class Period, defendants, pursuant to said scheme, plan, and unlawful course of conduct, knowingly and recklessly issued, caused to be issued, participated in the issuance

of, the preparation and issuance of deceptive and materially false and misleading statements to the investing public as particularized above.

39. As a result of the dissemination of the false and misleading statements set forth above, the market price of Genta securities was artificially inflated during the Class Period. In ignorance of the false and misleading nature of the statements described above and the deceptive and manipulative devices and contrivances employed by said defendants, plaintiff and the other members of the Class relied, to their detriment, on the integrity of the market price in purchasing Genta securities. Had plaintiff and the other members of the Class known the truth, they would not have purchased said securities or would not have purchased them at the inflated prices that were paid.

40. Plaintiff and the other members of the Class have suffered substantial damages as a result of the wrongs herein alleged in an amount to be proved at trial.

41. By reason of the foregoing, defendants directly violated section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon plaintiff and the other members of the Class in connection with their purchases of Genta securities during the Class Period.

COUNT II

For Violation Of Section 20(a) Of The Exchange Act
(Against The Individual Defendants)

42. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

43. The Individual Defendants acted as controlling persons of the Company within the meaning of section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, participation in and/or awareness of the Company's operations, and/or intimate knowledge of the Company's plans and implementation thereof, each had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that plaintiff contends are false and misleading. Each Individual Defendant was provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

44. In particular, they had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

45. By virtue of their positions as controlling persons, each is liable pursuant to section 20(a) of the Exchange Act. As a direct and proximate result of the wrongful conduct, plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

WHEREFORE, plaintiff, on his behalf and on behalf of the Class, prays for judgment as follows:

A. Declaring this action to be a proper class action and certifying plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of plaintiff and the other members of the Class against the Defendants for the damages sustained as a result of the wrongdoings of the Defendants, together with interest thereon;

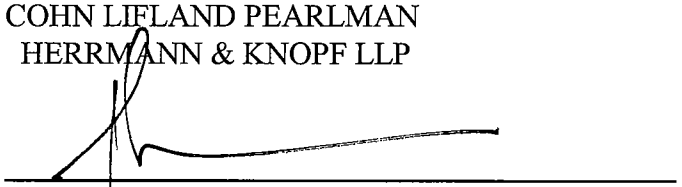
C. Awarding plaintiff the fees and expenses incurred in this action, including reasonable allowance of fees for plaintiff's attorneys, and experts; and

D. Granting such other and further relief as the Court may deem just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY

Dated: May 4, 2004

COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP

By: 

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Complaint.wpd

GENTA
CERTIFICATION PURSUANT TO THE FEDERAL SECURITIES LAWS

Earl Maitland ("Plaintiff") duly swears and says, as to the claims asserted under the federal securities laws, that:

1. I have reviewed a complaint to be filed against Genta and its senior officers. I approve of its contents, I authorize its filing, and I authorize Berger & Montague, P.C. to represent me.

2. I did not purchase the security that is the subject of this action at the direction of its counsel or in order to participate in this private action.

3. I am willing to serve as a representative plaintiff on behalf of the class, including providing testimony at deposition and trial, if necessary.

4. My transactions in the securities of Genta from September 10, 2003 through May 3, 2004 (the "Class Period) are as follows:

Shares Purchased	Date of Purchase	Price per Shares
1000	4/30/04	$9.90

5. I have not sought to serve as a class representative in any other action filed under the United States federal securities laws in the past three (3) years preceding the date on which this certification is signed.

6. I have not accepted and will not accept any payment for serving as a representative plaintiff on behalf of the class beyond its pro rata share of any recovery, or as ordered or approved by the court, including any award for reasonable costs and expenses (including lost wages) directly relating to the representation of the class.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 5 day of 4, 2004, at Cherry Hill (City), NJ (State).

By: _____
(Name)

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380471